

This document contains NIOSH responses to comments received on the draft version of the NIOSH Chest Radiography topic page. Posted March 2008.

I. THE COALITION FOR LITIGATION JUSTICE, INC.

A. Establish an Audit Program

Comment: In the case of ILO classifications made for litigation or contested proceedings, we find ourselves in disagreement with your position that “one of the most important components of reliable classification is selection of readers who are mainstream in their classification tendencies.” The problem faced by NIOSH does not concern B Readers who are mainstream in their classification tendencies. Instead, the problem NIOSH needs to address concerns doctors who accurately apply the ILO system when seeking B Reader certification and recertification, but who then choose to misread the films in an attempt to advance the litigation interests of claims that have no merit. The recent abuses by NIOSH certified B Readers in interpreting normal chest radiographs as evidence of silicosis described in our previous comments, and that were documented in the opinion by Judge Janis Graham Jack, were so egregious that the Judge characterized them as raising “great red flags of fraud.” We are confident that short of developing and implementing some type of audit program, these abuses will continue.”

We also take exception with your response that “It may be entirely appropriate for the courts, to make use of this guidance in an effort to establish quality of B Reader ILO classifications and qualifications of expert B Reader witnesses.” It is the NIOSH imprimatur that is conferred upon the individual that successfully completes the B Reader process, and as the certifying body, it is NIOSH that has a duty and obligation to ensure that persons certified use the credential correctly. To attempt to pass on this responsibility to the courts, or any other organization, is to abrogate NIOSH’s public health responsibility.

NIOSH has developed and implemented stringent quality assurance programs, to include field audits of approved devices, for its approval program for respiratory protective devices. It cannot be correct that NIOSH can develop quality assurance and audit programs for respirator certification but that NIOSH cannot implement a similar program for physicians being certified to interpret chest x-rays. We encourage NIOSH to revisit its decision not to implement an audit program for B Readers.

Response:

(The two statements quoted by the Coalition were in the NIOSH response to comments submitted after a previous version of the web site was posted).

NIOSH’s focus in developing this website is to promote practices that lead to reliable classifications of chest radiographs. The best way to ensure that classifications are of a high standard is to be proactive by building quality control into process of deriving

classifications. This is the direction favored by NIOSH and set forth in our website. Although the selection of readers is critical (as indicated in our earlier response), there are many other factors that have to be taken into account, including blinding, summarization procedures for multiple classifications, and number of readers.

Because the importance of procedural factors, post-hoc auditing of individual readers would not be sufficient to ensure that classifications were sufficiently accurate and reliable for their intended purposes. Moreover, auditing procedures are difficult and expensive to undertake properly. Such an activity could demand a very significant allocation of resources, taking away funding from our statutory research mission. There would be major questions of who to audit, when, and how (including how access could be gained to a representative sample of an individual reader's classifications). The analogy made by the Coalition to certification of respirators is not entirely applicable since, as noted by the Coalition, readers can deliberately change their behavior when being audited but respirators cannot.

The B Reader Program has always been limited to training readers and documenting their technical competence in ILO classification of chest radiographs through interval testing. Clearly, testing only provides information on whether a reader demonstrates a certain level of competence at a time when the reader is under direct observation. It is not, and can never be, an indicator or guarantee of future behavior. That is why it is so important that those undertaking or requesting classifications should be aware of the pitfalls and problems inherent in the process. If they are responsible for the acquisition of classifications, they should plan accordingly. If they are a user of such data, they should be ready to discount data not collected using appropriate methods.

B. Assist in Establishing a Panel of Experts in Pneumoconiosis Radiology to Serve as Court Appointed Experts

Comment: Nevertheless, NIOSH can still play a role in establishing a panel of experts in pneumoconiosis radiology to serve as court appointed experts. A unique service that assists federal and state judges in locating highly qualified independent scientific experts is offered by the American Association for the Advancement for Science (AAAS). Due to its success the Court Appointed Scientific Expert (CASE) program of AAAS, which began in 2001 as a demonstration project for federal district judges, was expanded in 2004 to state trial courts and assists in selecting experts on a case-by-case basis for judges. We recommend that NIOSH contact Deborah Runkle at CASE for additional information and to explore interest in assisting CASE in putting in place an expert panel on the radiology of the pneumoconiosis to assist the courts in obtaining independent scientists to provide medical opinions regarding chest radiography. <http://www.aaas.org/spp/case/case.htm>

Response

We appreciate the potential contribution that such a panel could make to the legal system. If CASE were to seek our expertise, we would consult with our attorneys regarding the

appropriate role for NIOSH, as a federal agency, in making recommendations for these panels.

C. Comments related to the Webpage, “Recommended Practices for Reliable Classification of Chest Radiographs by B Readers”

1. Subheading “Contested Proceedings – Remuneration”

Comment: Remuneration for ILO classifications in contested proceedings should be according to usual and customary charges for classification in other settings.

Response

Remuneration for classifications is based upon market forces, including the demand for and supply of B readers and the services they provide. Whatever the amount of compensation provided, the main issue is that there should be no financial incentive created for finding that a chest radiograph does, or does not, show evidence of disease. As noted in the B Reader Code of Ethics, “B Readers shall not accept compensation that is contingent upon the outcome of compensation proceedings or litigation for which they undertake readings.”

2. Subheading “Contested Proceedings – Reader Selection”

Comment: It is unlikely that parties to a contested proceeding will be able to agree to a selection procedure at random using the largest pool of B Readers available.

3. Subheading “Contested Proceedings – Number of Readers and Summary Classification”

Comment: It is unlikely that parties to a contested proceeding will be able to agree to the number of readers and a summary classification decision logic. This procedure would be practicable if using an independent panel of experts to serve as court appointed experts as recommended in II. B. above.

4. Subheading “Contested Proceedings – Blinding”

Comment: This is not conventional practice in litigation and it is improbable that the parties to a contested proceeding will be willing to consult with a B Reader without disclosing the alleged pneumoconiotic agent.

Response (items 2 through 4)

The NIOSH recommendations represent an approach that, if followed, would provide a degree of assurance that the classifications were reliable. We provided information on the limitations of the use of B readings in contested proceeding and then presented an

approach to address these limitations that may be useful to one or more litigants or to the presiding official in a contested proceeding.

5. Subheading “Contested Proceedings – Notification”

Comment: *We recommend adding to the end of the sentence “and recommend medical follow-up when appropriate.”*

Response

Suggestion adopted.

D. Comments Related to the Webpage, “Classification of Chest Radiographs: Practices for Medical Diagnosis”

1. Subheading “The Role of Classification of Chest Radiographs in Medical Diagnosis”

Comment: *We recommend adding a second paragraph that would read: “It is important to remember that chest radiograph findings alone are insufficient for the diagnosis of pneumoconiosis. Other data, such as the medical and occupational history, the physical examination, additional types of chest imaging, various laboratory tests, and biopsy results should also be considered.”*

Response

The text has been revised to make this point.

E. Comments Related to the Webpage, “Classification of Chest Radiographs: Practices for Epidemiologic Research”

1. Subheading “The Role of Classification of Chest Radiographs in Epidemiologic Research”

Comment: *We recommend the last sentence of the first paragraph be deleted since a discussion of surveillance and hazard investigations seems out of place in the section on epidemiology.*

Response

The text in the introductory paragraph has been revised to clarify that epidemiologic studies and related activities refers to health surveillance and health hazard investigations.

F. Comments Related to the Webpage, “Classification of Chest Radiographs: Practices for Worker Monitoring and Surveillance”

1. Introductory Paragraph, 4th Sentence

Comment: *We recommend that between the words “individual” and “may” the phrase “or the potential development of disease in coworkers” be inserted. This seems to be prudent public health advice based on a positive finding and makes broader use of the results of monitoring and surveillance.*

Response

The text has been revised to address this suggestion.

2. Subheading “The Role of Classification of Chest Radiographs in Worker Monitoring and Surveillance”

Comment: *In addition to these federal programs, state programs, such as the North Carolina Dusty Trades Program, and medical surveillance programs conducted by private industry and organized labor have been useful in the early detection of pneumoconioses and appropriate intervention. Indeed, with the possible exception of coal miners, probably far more workers are receiving periodic medical surveillance for the dust diseases through industry and labor efforts than through government programs.*

Response

The text has been modified to indicate that it applies to both public and private monitoring programs.

3. Subheading “Special Considerations for Classification of Chest Radiographs in Worker Monitoring and Surveillance Programs”

Comment: *In addition to safeguards for false positives, consideration should be given to obtaining a second interpretation on a percentage of normal films to guard against false negative readings.*

Response

This issue is covered more fully in the Quality Assurance section. The particular reference to false positives was intended as a “special consideration” for this section on worker monitoring and surveillance. It explains that follow-up reading of “positive” films serves to limit false positives. Also, it should be noted that the recommendation for number of readers does not specify multiple classifications only for positive films. It reads as follows: “Number of readers and summary classifications: A single B Reader classification of each chest radiograph is generally sufficient; additional independent classifications may be needed to ensure reliability within the program.”

G. Comments Related to the Webpage “Classification of Chest Radiographs: Practices for Determining Government Program Eligibility”

1. Subheading “Federal Black Lung Benefits Program”

Comment: We recognize that the ILO Classification is dated "2000" in the title but was published in "2002". In other places in the text the ILO Guidelines are cited as "(ILO 2000)". We recommend that NIOSH be consistent throughout.

Response

These inadvertent errors have been corrected.

2. Subheading “The Energy Employees Occupational Illness Compensation Program”

Comment: It is our understanding that under the Act, claimants for silicosis are limited to those involved for 250 days or more during the mining of tunnels in Nevada or Alaska (See § 7384r of the Act). To avoid misinforming workers at other DOE sites regarding eligibility, the worksite criterion should be addressed.

Response

The text has been revised accordingly.

H. Comments Related to the Webpage “Classification of Radiographs: Practices in Contested Proceedings”

1. Subheading “Remuneration”

Comment: Again, remuneration in excess of standard billing for comparable services should be discouraged.

Response

See previous response on this topic.

2. Subheading “Reader Selection”

Comment: As mentioned above, it is unlikely that the parties in a contested proceeding will be able to agree to a selection procedure at random using the largest pool of B Readers available.

Response

See previous response on this topic.

3. Subheading “Reader Selection”

Comment: As mentioned above, it is unlikely that the parties in a contested proceeding will be able to agree to a selection procedure at random using the largest pool of B Readers available.

Response

See previous response on this topic.

4. Subheading “Number of Readers and Summary Classification”

Comment: In contested proceedings, we agree that the initial interpretations should be obtained from independent readings, but we do not object to B Readers holding a conference to discuss a particular case after the individual interpretations are made.

Response

NIOSH does not object to conferences between readers undertaken after film classifications are obtained which follow the recommended guidelines, the original readings remain available and the principal summary classification is derived from those readings using a method representing the center of the distribution of the classifications.

a. Subheading 4.a. “Small Opacities”

Comment: Please justify why the higher reading of two independent readings of small opacities would be the final interpretation. It seems the difference could only be resolved by additional reading(s) of the case.

Response

Please note that the text has been slightly modified in the light of a separate comment.

We feel that the main issue occurs when two independent classifications are on different sides of a threshold criterion for abnormality used in a legal proceeding. If the two independent classifications both agreed that the radiograph showed or did not show abnormality according to the formal threshold criterion, it would not particularly matter which classification was chosen as the final one. However, if the two classifications differed on the presence or absence of abnormality as defined by the threshold criterion, it would matter greatly which classification was chosen as the final one. In that case, we recommend that a third classification be obtained and the median classification be taken as the final determination.

5. Subheading “Blinding”

Comment: This would be desirable but unlikely that it will be practiced in contested proceedings.

Response

See previous response on this topic.

6. Subheading “Notification”

Comment: *We suggest that notification come from the doctor interpreting the chest xray.*

Response

The principal issue is that it is ethically necessary that the individual be informed of their classification(s). With that understood, it is not critical from whom the notification comes. All parties engaged in the process of deriving classifications should agree on who has the responsibility for notifying the individuals concerned. This may be the physician or organization who requests the reading, or the B Reader, or some other entity.

I. Webpage, “Best Technical Practices “

1. Subheading “The Need for Good Quality Radiographic Techniques and Equipment”

Comment: *In addition to the Coalworkers’ X-ray Surveillance Program, guidance on technical quality is presented in Appendix A of the ILO Guidelines for Classification of Radiographs of Pneumoconioses with references to selected papers on producing quality radiographic images.*

Response

The information has been added.

II. Kenneth Rosenman

Comment: *The notification section of all types of readings not just medical diagnosis should include wording about reporting to public health. At minimum need language in notification in medical diagnosis in medical surveillance.*

Response

Suggestion adopted.

III. Charles Matthews

Comment: *My department has switched to filmless (digital) radiography. Should I indicate this in Box 1 for Film Quality? I assume this type of imaging is acceptable for*

ILO classification; the entire industry is switching to this modality. I would appreciate your comments.

Response

Digital radiography is discussed on the draft website at <http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

IV. Lawrence Repsher, MD

Comment: The entire B reading program has been perverted by deliberate grossly incorrect readings, especially in the medical-legal arena. This has been predominantly with the plaintiff's side, but also from time to time on the defense side. The bandaid proposed changes will have no effect in this area, because of the great financial and political pressures to continue to provide purposely false readings. The only solution that has any chance of success is a program with life and death teeth to curb this longstanding and current abuse of the system. There needs to be panel(s) to whom an aggrieved party can appeal to review specific x-rays, that have been submitted in a medical-legal process. This would allow for an accurate reading of the x-ray that would trump the original reading and for penalties up to and including loss of B reading certification for repeat offenders. The status quo has made the current B reading situation a national joke with attorneys for both sides hiring B readers that they know will read the films to their advantage no matter what the x-ray actually shows.

Response

We have described approaches on the web page that lead to readings that are as reliable as possible, including selecting B Readers randomly and not on the basis of known or suspected reading tendencies.

V. Allan R. Goldstein, MD

Comment: Having been certified since 1985, I find the study x-rays and syllabus are excellent and promote the concept of honesty and objectivity. The description of the program and its purpose are clear. You cannot be held responsible intellectually dishonest physicians.

Response

No revision required.

VI. Judith K Amorosa, MD

Comment: I am a chest radiologist who has been a B reader for over 20 years. Occupational exposure to the chest should be evaluated with Chest CT.

I have been collecting appropriate cases for this as I am sure many others also have materials to contribute.

Response

We agree that the chest CT can offer valuable clinical information not available on the chest x-ray, and the draft website comments on the importance of multiple modalities in the diagnosis of pneumoconiosis. This website, however, is focused on issues and best practices relating to classification of standard chest films by B Readers.

VII. Richard McWhorter

Comment: *It may be time to review the technical requirements for the radiographs and include the current state of radiography (i.e. digital imaging)*

Otherwise, no suggestions for improvement.

Response

Digital radiography is discussed on the draft website at <http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

VIII. Robert Ross

Comment: *Regarding CONTESTED PROCEEDINGS:*

I recognize that you put in many qualifying statements prior to discussing CONTESTED PROCEEDINGS but I am concerned that this section might be used (or even required) in the case of an individual law suit or become the way contested cases of possible pneumoconiosis are settled monetarily. I think this would be inappropriate for the reasons you give in the preamble (ie the ILO states specifically not to use the B-reading for these purposes and all the medical societies recognize that a medical diagnosis requires more than a chest radiograph in most situations).

I also feel you should emphasize that although the ILO system is a reasonable tool for mass screening and sometimes for epidemiological studies, the program does not teach B-readers something unique or special about reading chest x-rays. Many radiologists are more than well qualified to review a radiograph for evaluation of interstitial processes such as pneumoconiosis but are not NIOSH certified B-readers. Further, they often have the ability to follow up with other procedures such as CT scans of the chest which are generally more sensitive and specific than are chest x-rays. I am afraid the wording of your document implies certain abilities of chest x-rays and B-readers that do not exist. An individual involved in a law suit regarding a possible pneumoconiosis may wish to have an x-ray read by a B-reader or a group might decide to base case settlement on various factors (possibly including some kind of consensus reading by blinded or unblinded B-readers) but NIOSH should not imply that it is required or, if done as discussed in the section on CONTESTED PROCEEDINGS, will provide credibility to the diagnosis.

I believe NIOSH should have no policy recommendations regarding CONTESTED PROCEEDINGS other than the preamble. However, if you chose not to remove it, I would request that you state in this section some of the issues I brought up and that the suggestions you are making are not appropriate in litigation as this would give too much credence to the radiograph and the ILO readings.
[typos corrected]

Response

We appreciate these comments. The first paragraph of the web page on contested settings notes the limitations of chest radiography alone, “As in other settings, it is important to remember that chest radiograph findings alone are insufficient for the diagnosis of pneumoconiosis. Other data, such as the medical and occupational history, the physical examination, additional types of chest imaging, various laboratory tests, and biopsy results should also be considered, as available.”

With regard to ILO classification, authoritative statements exist that the ILO classifications are not meant to be employed for diagnosis or compensation. However, the fact remains that they have been and continue to be used that way. It was for this reason that NIOSH produced this guidance.

IX. Leslie Preger

*Comment: I liked the discussion of accuracy and precision. Would consistency be a better synonym for precision, as used in your B reader exam results?
[Personal information redacted by NIOSH] Hard copies 14x17 format or CDs continue to be used by many of us for B readings, since these are often the only images available to insurance companies, workers comp boards, attorneys, clinicians etc. Is it inappropriate to call these B Readings? Please answer this question.
Best wishes for your ongoing work.*

Response

We prefer precision because it has a statistical meaning.

The B Reader test is intended to ensure that readers can meet a certain standard of proficiency in performing ILO classification of chest radiographs, and does not, and cannot, monitor performance afterwards. For this reason NIOSH prefers to use the term “ILO classification of chest radiographs” and that the term “B Readings” not be employed. Regarding non-standard (presumably, digital) images digital radiography is discussed on the draft website at

<http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

X. Brent Harrison

Comment: In the ethics section, I suggest the comment about not making diagnosis from a chest film be made specific to occupational disease. We make diagnosis from chest

films daily. I recently had a lawyer accuse me of violating NIOSH ethics by interpreting a film as normal-normal=diagnosis???
[personal information redacted, by NIOSH.]

Response

We appreciate this comment. Clearly, some diagnoses, such as pneumothorax, can be made from a chest film. Suggestion adopted.

XI. John Heffner, MD, the American Thoracic Society

A.

Comment: The NIOSH web site on Chest Radiography is a concise and informative discussion of the ILO radiographic classification system for the pneumoconioses and other occupational lung diseases, and provides a valuable resource for physician training and communication. The web site includes sections on programmatic issues for B-reader certification; ethical considerations for B-readers; issues in classification of chest radiographs including reader variability, accuracy, precision and reader selection; recommended practices for reliable classification of chest radiographs; and references. There are several helpful links to other relevant resources and materials.

In response to initial reviewer comments, the revised web site has strengthened the discussion on methods for obtaining reliable radiographic classification. Particularly helpful is the section on Recommended Best Practices for the three principal settings involving chest radiography for pneumoconioses: (1) worker monitoring and surveillance; (2) epidemiologic research; and (3) contested proceedings. In each of these settings, the web site provides guidelines for reader selection, remuneration, use of multiple readers and summary classifications, blinded classification, quality assurance, and worker and employer notification. Regarding the issue of reader competency, NIOSH has wisely rejected recommendations for audit, decertification or expert panel systems, recognizing that the purpose of the B-reader program is not primarily to support the legal system. The B Reader Code of Ethics is helpful in articulating the framework in which B readers should adhere to professional standards.

Response

No revision required.

B.

Comment: In the section titled "Issues in Classification of Chest Radiographs", there is a discussion of blinding readers to knowledge of potential exposures and other information that may increase bias. This section seems to suggest that blinding is always recommended. However, as pointed out in the later section on "Recommended Practices for Reliable Classification", blinding is undesirable in the setting of worker monitoring and surveillance where disease detection should be facilitated. We recommend that the document be revised to reflect this exception and for internal consistency.

Response

The document has been revised to address this comment.

C.

Comment: Despite the value of this web-based chest radiography resource, it contains only a limited discussion of digital radiography, which has largely supplanted conventional film screen imaging at most large institutions. Digital radiography offers consistent high quality images, ready availability of identical copy images, and slight increase in sensitivity for micronodules when compared with conventional images. The ongoing real-world transition to digital radiographic imaging has made it difficult to utilize the current B reader system in medical surveillance programs and clinical epidemiologic research. ATS urges NIOSH to focus resources urgently to develop recommendations applicable to the use of digital images in the context of the ILO classification system.

Response

Digital radiography is discussed at

<http://www.cdc.gov/niosh/topics/chestradiography/breader.html>

D. Comment related to web page on medical diagnosis (found at:

<http://www.cdc.gov/niosh/topics/chestradiography/medical-diagnosis.html>)

Comment: Under the section on medical diagnosis, we believe that it would be appropriate to acknowledge that pneumoconiosis may be present with a normal or near-normal chest radiograph, and also that radiographic appearances may be nonspecific. CT may be helpful in clarifying such cases.

Response

Suggestion adopted.

E.

Comment: In the section on contested proceedings, the proposal for quality assurance is laudable but will be difficult to implement without a pool of images certified by expert readers- We are not aware that such a pool of images is currently in existence, and the term “expert readers” will require careful definition. Acceptable levels of variation from the test images would need to be defined. Similar considerations apply to the sections on epidemiologic research and worker monitoring and surveillance where the terms “calibrated images” or the even less clear “calibration images” are used.

Response

NIOSH is interested in pursuing the development of a pool of suitable quality control images but feels that this should follow the adoption of digital technology into the process of classifying radiographs using the ILO system.

The use of ‘quality control images’ (or calibration images) is analogous to using known standard materials to document the performance of scientific testing instruments. The insertion of such images into a batch of images to be evaluated permits one to assess the general performance of readers as compared to their expert peers.